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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
SCHELL, LAURA C	

ART UNIT	PAPER NUMBER
3767	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/785,348	SHELSO ET AL.	
	Examiner	Art Unit	
	Laura C. Schell	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 February 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12,16,17,19-27 and 29* is/are pending in the application.

4a) Of the above claim(s) *3,24 and 29-37* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 2, 4-12, 16, 17 and 19-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, 4-8 are rejected under 35 U.S.C. 102(e) as being anticipated by Griffin et al. (US 2003/0125751). Griffin discloses a medical device (Figs. 49 and 50) for slidable use with a guidewire (guidewire is 21; the examiner would like to point out that the Applicant has not positively recited the structure of the guidewire, as the guide wire is "for slidable use" with a medical device, and appears in the preamble which therefore means that the device that is positively claimed by Applicant (the medical device) only has to be capable of being used with the medical device in a slidable condition. Nevertheless, Griffin discloses all the limitations of the guidewire (Fig. 6a, 29; paragraph [0187] discloses that the guidewire has a stop on it)), the medical device comprising: an elongate tubular member (Figs. 49 and 50,210) having a proximal end (near 2) and a distal end (near 31) with a guidewire receiving lumen (7) extending therethrough, a distal portion of the guidewire lumen having an inner diameter of substantially the same magnitude as the first diameter (portion 13 clearly has a lumen within it that snugly

encompasses the diameter of the guidewire); and a tip (the tip beginning at where the portion 13 ends and the tip extends distally until the very distal-most part of 202) defining an annular wall (the lumen which 21 passes through is an annular wall) disposed at the distal end of the elongate tubular member, the tip having a first portion having a distal taper (the first portion is being interpreted as the portion between where the tip begins (at the end of 13) and extending until the beginning of 202, wherein there is clearly a distal taper in this first portion) and a radially inextensible ring distal of the first portion (202 is clearly distal of the first portion as interpreted by the examiner above; also see paragraphs [0266], [0267] and [0303]) wherein the annular wall of the tip has a thickness that decreases distally along a majority of the length of the tip (based on the definition of the tip defined above, the thickness of the tip decreases distally along the entire length).

In reference to claim 2, Griffin discloses that a therapeutic device (Fig. 6b, balloon 26) is disposed on the distal portion of the elongate tubular member.

In reference to claim 4, Griffin discloses that the first portion is softer and more flexible than a proximal portion of the medical device (Figs. 49 and 50 disclose that a hypotube (201) is used in the proximal portion of the medical device to stiffen it. Paragraphs [0266], [0267] and [0303] disclose that the first portion is a soft polymeric portion).

In reference to claim 5, Griffin discloses that the ring (202) is the distalmost portion of the tip (Figs. 49 and 50).

In reference to claim 6, Griffin discloses that the medical device is an angioplasty device (paragraph [0182]).

In reference to claim 7, Griffin discloses that the medical device is an intravascular filter (paragraph [0182]).

In reference to claim 8, Griffin discloses that the medical device is an intravascular guide catheter (paragraph [0070]).

Claim 25 is rejected under 35 U.S.C. 102(e) as being anticipated by Griffin et al. (US 2003/0125751). Griffin discloses a medical device (Figs. 49 and 50), comprising: an elongate catheter (Figs. 49 and 50,210) having a proximal end (near 2), a distal end (near 31), and a lumen (7) extending therethrough; and a tip (generally designated by reference number 31) defining an annular wall (the lumen which 21 passes through is an annular wall) disposed at the distal end of the elongated catheter, the tip extending distally of the distal end of the catheter (the distal end of the catheter is near 5), the tip comprising a soft body portion (the soft body portion is being interpreted as the portion between where 13 ends and the beginning of the ring member 202) and a rigid ring (202) distal of the soft body portion (as defined above, the soft body portion extends between the end of 13 and the beginning of 202. Since Applicant has used the word "comprising" to describe what the tip is made of, the tip can be made of more portions/elements other than just the soft body portion and the rigid ring, as "comprising" is considered more open-ended than "composed of". Therefore, while the rigid ring 202 may be surrounded by some soft material, it is still distal of the soft body portion,

wherein the "soft body portion" is defined as being between the end of 13 and the beginning of 202.), wherein the annular wall of the tip has a thickness that decreases distally along a majority of the length of the tip (based on the definition of the tip defined above, the thickness of the tip decreases distally along the entire length).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 9-12, 16, 17 and 19-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Van Tassel et al. (US Patent No. 4,531,943) in view of Muni et al. (US Patent No. 5,316,706). Van Tassel discloses a medical device (Figs. 4 and 5) capable of use with a guidewire (the examiner would like to point out that the Applicant has not positively recited the structure of the guidewire, as the guide wire is "for slidable use" with a medical device, and appears in the preamble which therefore means that

the device that is positively claimed by Applicant (the medical device) only has to be capable of being used with the medical device in a slidable condition), the medical device comprising: an elongate tubular member (Figs. 4 and 5) having a proximal end (10) and a distal end (26) with a guide wire receiving lumen (lumen 11 is perfectly capable of receiving a guidewire) extending therethrough, a distal portion of the guidewire lumen having an inner diameter; and a tip (28) disposed at the distal end of the elongate tubular member and having a distal end (25), a proximal end (near 28) and a lumen therethrough, the tip having an elastic portion (portion 24) and a radially inextensible distal portion (30) distal of the elastic portion (col. 4, line 40 through col. 5 line 7). Van Tassel, however, does not disclose that the lumen is a guidewire receiving lumen or that the tip comprises an amorphous polymer or that the radially inextensible distal portion comprises a locally crystalline section thereof.

Muni, however, discloses a catheter and method of making a catheter, in which softer sections are made from amorphous polymers and the hardened sections are made from crystalline sections (col. 3, lines 33-39 disclose the relationship between crystallinity and hardness, while col. 3, line 60 through col. 4, line 29 disclose that the crystalline and amorphous sections can be altered so that the catheter can have any pattern of hardness and softness). Furthermore, the lumen disclosed by Van Tassel (11) is perfectly capable of receiving a guidewire therein. Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Griffin with the method and pattern of hardening catheter sections by altering crystallinity, as taught by Muni, in order to provide another source of a hardened tip for

the catheter, especially since Van Tassel discloses that the material disclosed in Van Tassel is illustrative only and should not be considered as limiting the scope of the invention (col. 4, lines 36-39 and col. 5, lines 30-39).

In reference to claim 10, Van Tassel discloses that the radially inextensible distal portion (30) is an extremity (Figs. 4 and 5).

In reference to claim 11, Van Tassel discloses that the extremity is a distalmost extremity (Figs. 4 and 5).

In reference to claim 12, Van Tassel discloses that the radially inextensible distal portion comprises a ring (30) having a lumen (29) therethrough.

In reference to claims 16 and 17, as defined by MPEP 2113, product by process claims are not limited to the recited steps, only the structure implied by the steps. Therefore the distal portion is anticipated by Van Tassel.

In reference to claim 19, Van Tassel discloses that the radially inextensible distal portion comprises a non-compliant plastic band (col. 5, lines 2-7 disclose that it is a non-compliant band and col. 4, line 66 discloses it is made of plastic).

In reference to claim 20, Van Tassel further discloses that the tip further comprises a flexible portion (between 28 and 30) proximate the radially inextensible distal portion (30).

In reference to claim 21, Van Tassel also discloses that the radially inextensible distal portion is a distal-most extremity and wherein the flexible portion (portion designated generally as 24) is proximal of the radially inextensible distal portion, wherein the flexible portion tapers from a first outer diameter (diameter at 28) at a first

location along the tip to a second outer diameter (diameter at 27; col. 4, lines 55-57) less than the first outer diameter at a second location along the tip distal of the first location.

In reference to claim 22, Van Tassel further discloses wherein at the first location along the tip, the tip has a first thickness and a first inner diameter (Fig. 4 wherein the first location is at 28), and wherein at the second location along the tip distal of the first location (location at 27), the tip has a second thickness less than the first thickness and a second inner diameter greater than the first inner diameter (col. 4, lines 55-57 disclose that there is less material at 27 and Fig. 4 discloses that the inner diameter is greater here).

In reference to claim 23, Van Tassel discloses that the flexible portion comprises an inner surface concave in a first plane normal to a longitudinal axis and a second plane normal to the first plane (Fig. 4).

Claims 26 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Van Tassel et al. (US Patent No. 4,531,943) in view of Muni et al. (US Patent No. 5,316,706). Van Tassel discloses a medical device (Figs. 4 and 5) comprising: an elongate catheter (Figs. 4 and 5) having a proximal end (10) and a distal end (26), and an annular wall (24) defining a lumen (11, 27 and 29), wherein the transverse dimension of the lumen varies in size along a distal portion of the elongate catheter (portion of lumen 27 varies in size in a transverse dimension); a tip (24) disposed at the distal end of the elongate catheter having a first region that tapers distally (portion just to the right

of 24 tapers distally until 30) and a second region distal of the first region that tapers distally more sharply than the first region (the region starting at 30 and extending distally to 25, tapers more sharply than the first region) and the second region is a stronger region than the first region (col. 5, lines 2-7). Van Tassel, however, does not disclose that the first region is made fro an amorphous polymer and that the second region is made from a locally crystalline section thereof. Muni, however, discloses a catheter and method of making a catheter, in which softer sections are made from amorphous polymers and the hardened sections are made from crystalline sections (col. 3, lines 33-39 disclose the relationship between crystallinity and hardness, while col. 3, line 60 through col. 4, line 29 disclose that the crystalline and amorphous sections can be altered so that the catheter can have any pattern of hardness and softness). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Griffin with the method and pattern of hardening catheter sections by altering crystallinity, as taught by Muni, in order to provide another source of a hardened tip for the catheter, especially since Van Tassel discloses that the material disclosed in Van Tassel is illustrative only and should not be considered as limiting the scope of the invention (col. 4, lines 36-39 and col. 5, lines 30-39).

In reference to claim 27, Van Tassel discloses that the second region is the distal most portion of the tip (Fig. 4).

Response to Arguments

Applicant's arguments with respect to claims 1, 2, 4-12, 16, 17 and 19-27 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura C. Schell whose telephone number is (571) 272-7881. The examiner can normally be reached on Monday-Friday 9am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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